IX. 510(k) Summary

MAY 16 2001

SUBMITTER: DePuy AcroMed, Inc.
325 Paramount Drive
Raynham, MA 02780

CONTACT PERSON: Lisa A. Gilman

DATE PREPARED: April 6, 2001

CLASSIFICATION NAME: Appliance, Fixation, Spinal Interlaminal Orthosis, Spinal Pedicle Fixation

PROPRIETARY NAME: Moss Miami Spinal System

PREDICATE DEVICES: Moss Miami Spinal System (K953915, K982320, K982511, K982011, K983583, K992168)

INTENDED USE: The indications for use for the modified devices described in this submission are the same as those for the Moss Miami Spinal System cleared in 510(k) K992168. The indications are as follows:

When used as a posterior, noncervical hook, and/or sacral/iliac screw fixation system, or as an anterior, thoracic/lumbar screw fixation system, the Moss Miami Spinal system is intended to treat scoliosis, kyphosis and lordosis, fracture, loss of stability due to tumor, spinal stenosis, spondylolisthesis, a previously failed fusion surgery or degenerative disc disease (i.e., discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies).

When used as a pedicle screw fixation system of the noncervical spine in skeletally mature patients, the Moss Miami Spinal System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Moss Miami Spinal System is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5 – S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3 – S1), and for whom the device system is intended to be removed after solid fusion is attained.

MATERIALS:

Manufactured from ASTM F-136 implant grade titanium alloy and ASTM F-138 implant grade stainless steel.

PERFORMANCE DATA:

Performance data were submitted to characterize the modified Moss Miami 4.35mm diameter screws.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2001

Ms. Lisa Gilman
Regulatory Affairs Associate
DePuy AcroMed
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K011182
Trade/Device Name: Modified Moss Miami 4.35mm Diameter Polyaxial Screws
Regulation Numbers: 21 CFR 882.3070 and 888.3050
Regulatory Class: II
Product Codes: MNH, MNI and KWP
Dated: April 13, 2001
Received: April 18, 2001

Dear Ms. Gilman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. Indications for Use

510(k) Number (if known): K011182

Device Name: Modified Moss Miami 4.35mm Diameter Polyaxial Screws

Indications For Use:

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(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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510(k) Number K011182

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use:
(Per 21 CFR 801.109)